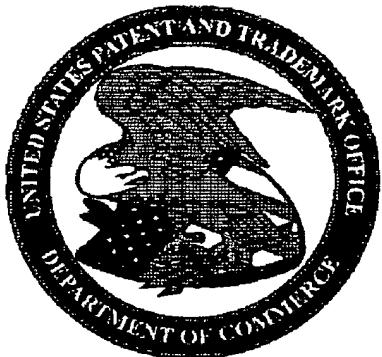


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PHONE: 602-382-6377

RE: U.S. Serial No. 09/808,314

MESSAGE:

Examiner Counts: Attached is a copy of the Declaration of Randall W. Nelson. If you have any questions regarding this declaration, please don't hesitate to contact me.

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IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

PATENT

Applicants: Randall W. Nelson et al. Docket No.: 41821.0238 RECEIVED
Serial No.: 09/808,314 Examiner: Gary W. Counts CENTRAL FAX CENTER
Filed: March 14, 2001 Art Unit: 1641 FEB 05 2005
Title: MASS SPECTROMETRIC IMMUNOASSAY

DECLARATION OF RANDALL W. NELSON

I, Randall W. Nelson, hereby declare as follows:

1. I am a co-inventor in application having Serial No. 09/808,314 along with Peter Williams and Jennifer Reeve Krone.

2. I have reviewed the paper entitled "Direct Analysis of Affinity-Bound Analytes by MALDI/TOF", Anal. Chem. 1994, 66, 2609-2613 authored by Papac et al. and this reference fails to disclose quantifying the amount of one or more analytes using only mass spectrometry. Furthermore, Papac et al. does not disclose using mass spectrometry for identifying an unknown analyte as claimed by the instant application in that the analyte which is analyzed in Papac et al. is already known.

3. I have also reviewed the publication authored by Gaskell in Steroids, 55:458-462, 1990. The 1990 Gaskell reference discloses quantification of DHA-S in serum using fast atom bombardment (FAB)/tandem mass spectrometry. The quantification method includes: (1) stable isotope dilution using an internal standard, (2) isolation of the analyte by immunoadsorption, namely highly selective retention on a solid phase incorporating bound antiserum raised against a conjugate of DHA, and (3) detection of both analyte and internal standard during limited mass range parent ion scanning during tandem MS. (See page 460 of the reference). Accordingly, the 1990 Gaskell reference teaches away from the instantly claimed invention by using tandem MS for quantification. In other words, different mass spectrometric measurements are taken of similar portions of the same serum extract and compared. (See page 461 of the reference). Unlike the instant claimed invention, the analyte and IRS are not measured using MS in a single measurement. In addition, the 1990 Gaskell reference also teaches away from the instant

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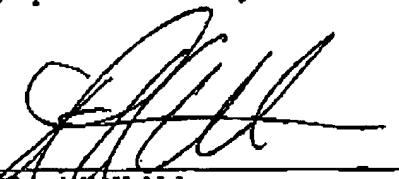
PAGE 03/03

claimed invention by requiring multiple sample preparation steps in between extraction and mass spectrometry. (See pages 460-461 of the reference).

4. The prior art references that have been cited in the prosecution of this application have used dual forms of separation. For example, the 1990 Gaskell reference uses mass spectrometry as a separation step which is then followed by mass spectrometry for mass detection. In another example, the 1983 Gaskell et al. reference entitled "Amino Adsorption to Improve Gas Chromatography/High-Resolution Mass Spectrometry of Estrodial-17B in Plasma", Clin. Chem. 29/4, 677-680 utilizes gas chromatography as a separation step which is then followed by mass spectrometry for mass detection. The instant application involves performing separation and detection in one mass spectrometric step. The identification and quantification of an analyte(s) is determined using only single dimension mass spectrometric analysis.

5. I further declare that all statements made herein of my own knowledge and that all statements are made on information and belief as believed to be true; and further that these statements were made with a knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Dated: 12/29/2004


By: Randall W. Nelson

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